Demographics and Baseline

Mean Age	86,33 years
Gender	all female
EuroScore	22,4 %
Table 1	

Results post implantation

Mean AVP	8,97
Max. AVP	14,74
Table 2	

Conclusion: The JenaValve™ TAVI system is a new generation transcatheter valve, allowing precise valve by positioning feelers. The low profile prosthesis, the self expanding stent design and the possibility of partial repositioning provide procedural safety which is reflected by the 30-day survival of all 9 transapical pat. .

TCT-334

Remote Controlled Robotic System for Trans Septal Puncture: In Vivo Evaluation

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Background: Trans-septal puncture (TS) is required for cardiac interventions such as mitral valvuloplasty, pulmonary vein ablation and left atrial appendage closure. However, the technique for TS requires a high level of skill set with significant experience and dexterity for optimum results. Magnetic systems have been developed to assist catheter positioning in electrophysiology but application in interventional cardiology has been limited. In this study, we sought to investigate the feasibility of a robotic catheter for TS with a remote control joystick in a porcine model.
Methods/Results: The automatic navigation platform (ANP) composed of a robotic system and custom software (CathNav) for joystick guided manipulation of a robotic needle by computer interface. A standard Brockenbrough needle was used with two Aurora sensors attached to its distal shaft. The needle was deployed on the robotic assembly and advanced to the RA through the femoral vein. ANP utilized Aurora electromagnetic tracking system to track the intra cardiac position of needle. A third Aurora sensor (ref sensor) was introduced in the left atrium (LA) through the retrograde approach using a guide catheter. Intracardiac echo catheter was used for real time image acquisition. The ref sensor in the mid LA was the target of remotely guided TS. At any instant, the distance between the needle tip and the ref sensor was reported through the CathNav interface to assist the joystick operator in controlling needle position under echocardiographic guidance. The needle was manipulated using the ANP joystick to contact ref sensor in the LA from a mid right atrial position. The initial and final distance between the needle tip and the reference sensor were recorded along with the duration of the navigation task. To interatrial septum was crossed six times using this technique. At the end of experiment, macroscopic examination was completed for location of TS and assessment of damage to intra cardiac structures. Interatrial septum was crossed successfully in all attempts using ANP remote guidance. The average time for TS was 2.3±0.5 minutes. Post mortem examination determined the location of all TS attempts to be within 0.5 cm radius without damage to sorrounding tissue.
Conclusion: A joystick enabled robotic navigation using ANP demonstrates adequate in vivo performance using standard Brockenbrough needle for precise TS. This technology may be helpful in improving the safety of complex intra cardiac interventions by decreasing reliance on operator skill and dexterity.

TCT-335

Novel arterial puncture and closure system: First experience in 1000 patients worldwide

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Background: Obtaining hemostasis at the arterial puncture site with closure devices has the potential for causing infection and embolic events as well as bleeding, hematoma, pseudoaneurysm, and various other vascular complications.
Method: We report on a new Vascular Access Device that allows to create a pathway for the guide wire into the vessel lumen passing through the vessel wall. The Arstasis device (Arstasis, San Carlos) has an integrated needle that traverses through the vessel wall and into the vessel lumen. A sheath is then advanced over the provided guide wire and the scheduled procedure commences. After the procedure the sheath is removed and the blood pressure closes the subintimal space and therefore the puncture site. Goal is accessing the common femoral artery, and to achieve hemostasis in conjunction with standard manual compression. During compression vascular closure time was measured at approximate intervals of 1, 3, 6 minutes or until access site was closed.
Results:1191 Patients (67% m) mean age 59y ± 12 y, were treated with the device in mainly diagnostic catheterization procedures (73%) compared to interventional procedures (26%). The majority of patients received antiplatelet therapy (82.6%), 17.4% on Aspirin alone, 58.9% on Aspirin and Clopidogrel and 6.3% on Clopidogrel alone. About half had no prior access to the groin (43%), the majority 1-2 sticks (41%) and multiple sticks (16%). Mean time to hemostasis was 4.9 min (n=1008, range 0-28 min.) for diagnostic and interventional patients. [Break down by diagnostic and interventional patients to follow.] Overall device related complication rate was 2.01%. Major device related complications were pseudoaneurysm requiring intervention (3/1191, 0.25%) and surgical repair of a severed side branch (1/1191, 0.08%) for a total major complication rate of 0.34%. Minor device related complications were groin hematoma >6 cm (9/1191, 0.76%), followed by subclinical pseudoaneurysm (4/1191, 0.34%), AV-fistula (3/1191, 0.25%), re-bleed (3/1191, 0.25%), and transient neural pain (1/1191, 0.08%) for a total of 1.68%.
Conclusion: Treatment with this new access and closure device results in an acceptable overall compression time and complication rate. This device uses only anatomical structures to accomplish hemostasis and could be a very effective support for routine catheterization procedures.

POSTER

Invasive Imaging

(Abstract Nos 336-370)

TCT-336

Para-Strut Leukocyte Infiltration Correlates with Increased Presence of Peri-Strut Low Intensity Area by OCT in the Coronary Familial Hypercholesterolemic Swine Model

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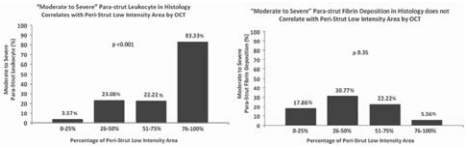
Background: Para-strut leukocyte (PSL) infiltration within stents neointima has been previously reported in pathology of animal and human restenosis. PSL presence has been associated to hypersensitivity reaction leading to granuloma formation. Para-strut fibrin deposition (PFD) is the pathologic hallmark of drug effect and has been associated to delayed healing. Low intensity areas (PLI) around the struts are commonly seen in OCT evaluation in vivo. In this study, we aimed to analyze the correlation between PLI in OCT with the presence of PSL and PFD among stents implanted in a familial hypercholesterolemic swine model (FHS).
Methods: 25 stents were implanted in the coronary arteries of 9 FHS using 30 second balloon inflations (x3) with a balloon-artery ratio of 1.3:1 prior to stent placement. At termination, stents underwent OCT analysis and histology. For OCT analysis, PLI was defined as a homogenous low intensity signal surrounding stent struts without significant attenuation behind it and its percentage was determined. In histology, PSL and PFD were determined using a semi quantitative score (None, Mild, Moderate, Severe).
Results: Stent sections displaying the highest number of struts with PLI (76-100%) correlated with the highest percentage of PSL infiltration (83.3%; p<0.001). Stents displaying the lowest level of PLI had the lowest degree of moderate to severe PSL infiltration (3.57%). In contrast, there seemed to be no correlation with the presence of moderate to severe PFD in any of the stent sections to any level of PLI presence.



Conclusions: The presence of PLI in OCT appears to correlate with the presence of moderate to severe PSL infiltration. There seems to be no correlation with the presence PFD. PLI areas seen by OCT may be able to predict the pattern of vascular healing of stents in vivo if proper analytical tools can be developed.

TCT-337

Measuring the Diameter Of the Aortic Valve Using the EndoFLIP® Endolumenal Measurement Catheter

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Background: There exist challenges in the accurate sizing of percutaneous arterial valve prostheses, since standard valve sizers can no longer be used for such procedures, leading to a reliance on non-invasive techniques such as TEE and CAT which give conflicting results. We have used EndoFLIP (Crospon, Galway, Ireland), a new endolumenal measurement catheter , to measure the diameter of the aortic annulus of embalmed cadaver hearts. We sought to investigate the ability of the EndoFLIP catheter to accurately measure this diameter by comparing the diameter measurements recorded using EndoFLIP with measurements taken using traditional mechanical sizers.
Method: 11 human embalmed cadaver hearts were selected for this study. An EndoFLIP model EF-325 balloon catheter was used, which has a solid state pressure sensor and 16 diameter measurement electrodes. Diameter is measured electrically using the principal of *impedance planimetry*, which permits the balloon pressure to be independently set to a desired distending pressure, and the valve diameter to be measured at that pressure. The balloon was inserted through the aorta into the right ventricle and positioned so that it was centred at the valve cusps. The balloon was then successively inflated to pressures between 30 and 130mmHg to obtain the annulus diameter at each pressure. The valves were then measured using the mechanical sizers. The sizers were capable of giving measurements in 1-mm increments.
Results: An analysis of the data, at each pressure tested, produced the following table:

Pressure (mmHg)	Mean Difference (EndoFLIP - Sizer) (mm)	95% Confidence Interval	Standard Error
30	-4.33	-6.474 to -2.192	0.9827
50	-2.492	-4.297 to -0.686	0.8289
70	-1.221	-2.809 to 0.367	0.7287
90	-0.891	-2.368 to 0.586	0.6779
95	-0.674	-2.105 to 0.757	0.6566
100	-0.652	-2.078 to 0.775	0.6546
105	-0.638	-2.059 to 0.784	0.6523
110	-0.546	-1.922 to 0.830	0.6316
115	-0.164	-1.61 to 1.282	0.6569
120	0.066	-1.358 to 1.491	0.6394
130	0.255	-1.143 to 1.652	0.6271

Conclusion: At pressures of 90mmHg and above the difference between the EndoFLIP measurements and mechanical sizer measurements is not statistically different. Optimum accuracy is obtained at 120mmHg balloon inflation pressure.